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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,737	08/17/2000	Eva-Maria Mandelkow	28384/36668	5085

7590 09/20/2005

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/640,737	MANDELKOW ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37, 42, 44 and 49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37, 42, 44 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

scw

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DETAILED ACTION

Formal matters

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Response to Amendment

2. Claims 37 and 44 have been amended as requested in the amendment filed on August 03, 2005. Following the amendment, claims 37, 42, 44 and 49 are pending in the instant application.

Claims 37, 42, 44 and 49 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on August 03, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 103

6. Claims 37, 42, 44 and 49 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kosik et al. in view of Harlow and Lane, 1988 for those reasons of record in section 10 of Paper mailed on June 10, 2004 and in section 8 of Paper mailed on January 31, 2005.

Applicant traverses the rejection on the premises that the instant claims, as amended to recite the ability of the antibody to distinguish "between phosphorylated and dephosphorylated

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tau”, and also limitation “consisting essentially of” distinguish the instant claimed invention and prior art of Kosik et al. (see pages 6-7 of the Response). Applicant’s arguments have been fully considered but are not persuasive for the following reasons.

As fully explained in the previous office actions of record, claims 37, 42, 44 and 49 are broadly drawn to a composition comprising a peptide comprising tau peptide. According to MPEP, phrase “consisting essentially of” with respect to amino acid sequences is construed as equivalent to “comprising” (MPEP 2111.03). Furthermore, since the instant specification does not provide any limiting definitions of “a peptide consisting essentially of [amino acid sequence 259-267 of SEQ ID NO: 1]”, by broadest reasonable interpretation, the instant claims would appear to be directed to an immunogenic composition comprising tau protein. Thus, Applicant’s arguments that “consisting essentially of” limits the structure of the peptide in the claimed composition are not persuasive.

Furthermore, new limitation as presented in the amended claims 37 and 44 (“distinguishes between phosphorylated and dephosphorylated tau”) does not appear to change the scope of the claimed invention with respect to the structure of the components within the instant composition. One skilled in the art readily understands that the ability of an antibody to distinguish between phosphorylated and dephosphorylated tau is limited to the ability of an antibody to specifically recognize the presence, such as in the instant case, or absence of the phosphorylated epitope. Applicant is advised that claims 37 and 44, as presented, raise issue of potential lack of enablement of the claimed invention for not disclosing how to produce an antibody that distinguishes phosphorylated tau by using a peptide lacking phosphorylated residue at position 262 (see reasoning in section 10 of the instant office action).

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7. Claims 37, 42, 44 and 49 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Vooheis, US Patent No.5, 492,812 ('812 document) for reasons of record in section 11 of Paper mailed on June 10, 2004 and in section 9 of Paper mailed on January 31, 2005 and also in section 6 of the instant office action as applied to answer Applicant's arguments in section II of the Response.

New grounds of rejection necessitated by amendment

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 37, 42, 44 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 37 and 44, as amended, are vague and indefinite because the metes and bounds of the newly presented limitation "[an antibody] which distinguishes between phosphorylated and dephosphorylated tau" cannot be determined from the claims or the instant specification.

Specifically, one skilled in the art readily appreciates that specificity of an antibody is determined by ability to bind to a particular epitope. For example, if an antibody specifically recognizes an epitope with phosphorylated Ser at position 262 within the SEQ ID NO: 2, then that antibody would bind to this epitope, thus determining the presence of phosphorylated tau. Therefore, it is not clear what constitutes "an antibody which distinguishes between phosphorylated and dephosphorylated tau". Clarification is required.

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11. Claims 42 and 49 are indefinite for being dependent from indefinite claims.

Conclusion

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

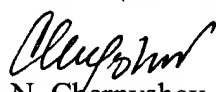
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

September 16, 2005